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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,546	03/20/2001	Karl Kolter	51284	9100

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EXAMINER	
SILVERMAN, ERIC E	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
09/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/811,546	KOLTER ET AL.	
	Examiner	Art Unit	
	ERIC E. SILVERMAN	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-14,16-18 and 22-34* is/are pending in the application.

4a) Of the above claim(s) *25 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-14,16-18,22-24 and 27-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 9/5/2008 has been entered.

Claims 1, 3-14, 16-18, 22-34 are pending, claims 25 and 26 are withdrawn, and claims 1, 3-14, 16-18, 22-24, 27-34 are treated on the merits in this action

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims1,3-174,16-18,22-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 now includes the limitation "wherein said delayed release is defined as limiting the amount of active ingredient released in the first hour to 25.3% *based on the weight of the oral dosage form*." (emphasis added) Support for this amendment is allegedly found at table 12 (9/5/2008 response at 11). Table 12 does not give the basis for the amount of active released; it does not specify whether this amount is based on the weight of the dosage form or the weight of the loaded active. As such, there is no support for the new limitation.

Claims 1 and 34 include the limitation "pre-formulated mixture". While the originally filed disclosure supports a formulated mixture, Applicants' have not alleged, and the Examiner is unable to locate, any support for a "pre-formulated mixture."

The remaining claims are ultimately dependant on claim 1, and are rejected for incorporating the new matter of claim 1 by dependency.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 recites the limitation "water-soluble or lipophilic polymers" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 30 specifies the nature of "lipophilic additives". The additives mentioned, however, such as fatty acilcohols, glyceries, waxes, etc. are lipophobic, not lipophilic.

Claim Rejections - 35 USC § 102

Claims 1, 4, 7,-12, 14, 16-18, 22, 24, and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,837,032 to Ortega.

Claim 1 requires an oral dosage form with delayed release, as defined therein, comprising (a) one or more actives; (b) from 20 to 80% by weight a formulated mixture of PVAc and PVP; (c) water soluble polymers or lipophilic additives, and (d) other conventional excipients.

Ortega discloses, in claim 10, a tablet containing 50% acive agent (theophylline), 15% PVAc, 15%PVP (total of 30% PVAc and PVP), 15% celluloe acetate phthalate (lipophilic additive per instant claim 24) and 5% lubricant, where the lubricant is, in Ortega claim 5, talc, fatty acids, etc (conventional excipients). The PVP/PVAc are "pre-formulated mixture" within the scope of that term according to the methods of making in the examples, where the materials are intimately blended. The composition of Ortega is that of the claimed invention. Identical compositions cannot have mutually exclusive properties, and thus Ortega's composition must have the claimed delayed release profile, hardness, friability, etc.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-14, 16-18, 22-24, and 27-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 197 09 663 to Kolter (of which US 6,066,334 is relied on as a translation) in view of US 4,837,032 to Ortega.

1. Previously rejected claims 1, 3-14, 16-18, 22-24, and 27.

In accordance with the decision of the Board of Patent Appeals and Interferences filed 7/10/2008 and the principle of *res judictica*, the only potential basis of patentability of these claims is in the amendments. See MPEP 706.03(w). The amendments alter the claims by requiring (1) a "*pre*-formulated mixture" of polyvinylpyrrolidone and polyvinyl acetate ("PVAc"), instead of a "formulated mixture" as previously claimed, and (2) that delayed release be defined as release of no more than 25.3% of the active agent, based on the total weight of the dosage form, in the first hour. These new limitations are addressed individually below.

(1) The term "pre-formulated mixture" does not appear in the original disclosure. Nonetheless, Kolter's teaching of finely distributing PVAc in PVP is understood to be within the scope of a "pre-formulated mixture".

(2) It is acknowledged that Kolter does not teach the claimed release rate. However, Ortega teaches that the amount of binder is a result-effective parameter, that could be altered to vary the release rate based on the intended use of the intended use of the final product. Ortega shows in the various examples that increasing the amount of binder will lengthen the release profile (thus lowering the amount of active released in the first hour). Ortega also suggests that this could be accomplished by adjusting the ratio of PVP to PVAc in the binder. To wit, Ortega teaches that PVAc "serves as a

retardant against drug dissolution" and that PVP "swells and dissolves thereby permitting controlled drug dissolution as the gastro-intestinal fluids penetrate and erode the tablet" (Ortega col. 3, lines 11-17, BPAI decision page 6). As such, adjusting the release profile of Kolter is no more than manipulating a results effective parameter in a predictable fashion. Indeed, Kolter notes that "[t]he disintegration and release properties of pharmaceutical compositions prouced with the products according to the invention [the PVP/PVAc binder] do not different from comparable compositins with conventional binders." Accordingly, the artisan who would know how to manipulate conventional binder amounts to give a desired result would be able to do the same with PVP/PVAc binder. This notion is supported by the Remington reference, of record, which indicates that it is a general tenant of art that increasing the amount of binder will slow the dissolution time of a tablet.

2. Newly added claims 28-33

Instant claim 28 requires that the water soluble polymers or lipophilic additives of claim 1 do not include PVAc or PVP. Kolter teaches the use of 0-20% of another water soluble or water swellable substance (another being understood to mean other than the required PVAc and PVP), Kolter also teaches the use of magnesium stearate, the salt of a fatty acid. Example 4 also teaches the use of a vinylacetate/vinylpyrrolidone block copolymer, as per instant claim 29. With regard to claim 31, this is a product by process claim; as there is no evidence of record indicating that production of the claimed dosage form by extrusion gives a different result than production by tabletting (as in the applied art), the process step is not a basis for patentability. With regard to claims 32 and 33,

these claims list properties of the product, which must also be properties of the suggested product having the same composition. Notably, Kolter suggests that PVP/PVAc combinations give low friabilities and high hardness. Col. 4, lines 41-46.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive. Applicants' argue that the various new limitations of the amended claims are not taught or suggested by the art. Each new limitation has been addressed above.

Claims 1, 3-14, 16-18, 22-24, and 27-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kolter in view of Ortega, as applied to claims 1, 3-14, 16-18, 22-24, and 27-33 above and in further view of US 4,816,259 to Matthews.

What is lacking from Kolter and Ortega is a teaching of a coating.

Matthews teaches that coating solutions such as PVP and PVAc, can be used to readily coat tablets and pills, in order to protect ingredients, improve appearance, mask against unpleasant taste or odor, and other reasons. Col. 1.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to coat the tablets of Kolter and Ortega with PVP/PVAc according to Matthews. Obviousness stems from Matthews teaching of various advantages stemming from such a coating.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is

(571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/
Examiner, Art Unit 1618